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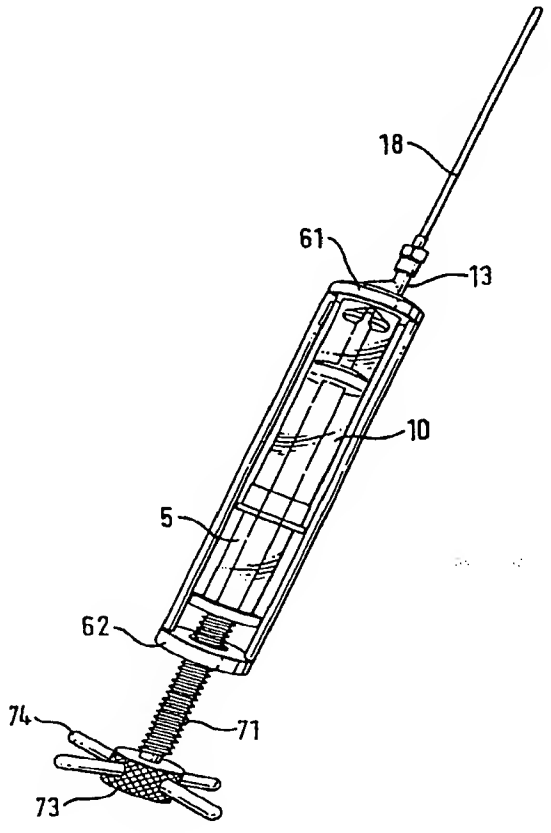
(54) Title: AN APPARATUS FOR MIXING AND DISPENSING INGREDIENTS

(57) Abstract

An apparatus which is particularly useful for the mixing of hydroxyapatite cement comprises a syringe body (10) within which a plunger (5) is slidably and sealingly located for expelling the syringe contents, the plunger having an axial passageway and the shaft (2) of an agitator (4) extending therethrough. The agitator has a head portion (25) designed to cause materials (8) contained in the chamber defined between the inner end of the plunger and the syringe interior to be mixed when the actuator is agitated by manual operation of the agitator shaft where it is accessible outside of the plunger. To facilitate dispensing of the mixture, the apparatus can be received in a support frame (60) having a turnscrew (72) at one end enabling the plunger to be operated with mechanical advantage. A removable end cap (16) seals the mixing chamber (8) during mixing and the mixture can be dispensed through an elongate tube into limited access locations.



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AN APPARATUS FOR MIXING AND DISPENSING INGREDIENTS

Field of the Invention

This invention relates to an apparatus for mixing and dispensing ingredients, particularly though not exclusively for mixing and dispensing hydroxyapatite cement.

Background of the Invention:

It is well known to use hydroxyapatite cement (hereinafter also referred to as BoneSource (Registered Trade Mark)) to fill any non-load bearing bone void with the exception of those anatomical areas contacting the central nervous system or central circulatory system of the human body.

The preparation of BoneSource hydroxyapatite cement requires that immediately prior to application into a bone void, BoneSource powder is mixed with a liquid curing agent under sterile conditions. The mixing of these ingredients is usually achieved by manually stirring of the ingredients in a beaker until a doughy consistency has been obtained. Typically, a 10 gram package of BoneSource powder is mixed with 2.5 to 3.0 mls of a liquid curing agent.

It is well known to apply the mixed BoneSource to a bone void by forming a ball of the doughy mixture with the fingers and then manually packing the doughy mixture into the void from the most convenient point on the external surface of the bone in the region of the fracture.

Such a mixing process has proven to be both wasteful and difficult to operate because powder or liquid may be spilled from the beaker during mixing, proportions of the ingredients which are to be mixed may not be completely mixed and the doughy consistency required of the mixed ingredients may vary. In addition, there are certain surgical procedures for which access to the bone void into which the BoneSource is to be applied is severely limited.

Objects and Summary of the Invention:

It is an object of the present invention to provide an apparatus and method of mixing and dispensing mixed constituent materials which enables the above difficulties to be eliminated or at least substantially reduced.

According to the present invention there is provided an apparatus for mixing and delivery of constituent materials, said apparatus comprising first and second relatively moveable body portions which together are capable of defining a mixing chamber therebetween, and agitator means locatable in the mixing chamber for mixing together ingredients introduced into said mixing chamber, characterised in that the agitator means includes a limited region intermediate opposite ends thereof for allowing gas release from the mixed ingredients and being arranged to extend externally of the mixing chamber for enabling actuation of the agitator means and the body portions being movable relative to each other to reduce the volume of said mixing chamber for dispensing mixed ingredients therefrom.

In a preferred embodiment of the present invention which will be described in detail hereinafter the agitator means comprises an elongate shaft which extends into the mixing chamber and has a head formed to mix the contents of the chamber when the shaft is vigorously reciprocated. The head of the agitator may for example comprise a conically shaped body having a plurality of radially extending flutes for the passage therethrough of the materials being mixed. Alternatively, the head may simply be a circular disc.

Conveniently the limited region is intermediate the opposite ends of the agitator shaft and includes reduced thickness portion having a flat surface to provide a gap between the agitator shaft and the second relatively movable portion to facilitate passage of gas from the mixing chamber.

The first and second relatively movable body portions preferably comprise a cylindrical container open at one end and closed at its opposite end except for the provision of a sealable nozzle through which the contents of the

container may be dispensed, and a plunger sealingly engaged in said container and movable axially thereof, the agitator shaft being arranged to pass substantially sealingly through an aperture in the plunger.

The cylindrical container can conveniently comprise a standard syringe body and the plunger can conveniently comprise a substantially standard syringe plunger formed with an elongate passage therethrough for the agitator shaft. An elongate dispensing tube may be connectable to the nozzle of the syringe to enable the mixed syringe contents to be accurately dispensed into difficult locations.

To facilitate dispensing of the mixed syringe contents which, as aforementioned, may have a relatively stiff consistency, a support means for the syringe may be provided, the support means having provision for operating the plunger of the syringe with a mechanical advantage. In the hereinafter described embodiment, the support means is a frame within which the syringe may be received with a manually operable turnscrew mounted in the frame and bearing upon the plunger for moving the plunger inwardly of the syringe body to dispense the mixed constituent materials through the nozzle of the syringe.

The abovementioned embodiment of the present invention will now be described by way of example with reference to the accompanying drawings.

Description of the Drawings:

Figure 1 is a side elevation view of a mixing and dispensing device in accordance with the present invention;

Figure 2 is a side elevational view of the device of Figure 1 together with a means for facilitating dispensing of the mixed contents from the device;

Figure 3 is a view similar to Figure 2 but in which the end cap of the device has been replaced by a dispensing tube;

Figure 4 is an external view of the end cap which is mountable on the device to seal it during mixing;

Figure 5(a) is a side elevation view of an agitator for mixing ingredients introduced into the device and Figure 5(b) is an end elevation view of a conical head end of the agitator;

Figure 6 is a side elevational view of a tommy bar to be used with the agitator;

Figure 7(a) is a side elevation view of a central plunger of the device, Figure 7(b) is an end elevation view and Figure 7(c) is a side elevational view of a rubber seal mountable at one end of the plunger;

Figure 8 is a side elevational view of a support frame adapted to hold the device;

Figure 9 is a side elevation view of a pressure screw to be used with the support frame of Figure 8 for moving the central plunger of the device;

Figure 10 is a side elevation view showing an alternative two part end cap;

Figure 11 is a side elevation view showing the end cap of Figure 10 affixed to the end of a syringe body; and

Figures 12(a) and 12(b) are side and end elevation views respectively of an alternative agitator head.

Detailed Description of the Embodiment:

Referring to the drawings, there is illustrated in Figures 1 to 3 an apparatus for mixing and delivering a mixture of constituent materials, for example for making hydroxyapatite cement. The apparatus comprises an elongate hollow body 1 which is closed at one end and open at the other, and an elongate, rounded agitator paddle 2 locatable within the body and having at its outer end 3 an elongate bar 4 removably received in a hole in the agitator shaft and arranged to extend transversely of the longitudinal axis of the of the agitator shaft so as to enable the agitator paddle to be moved in a longitudinal or rotational direction relative to the longitudinal axis of the hollow body 1 for mixing ingredients added separately into the body 1.

A dispensing plunger 5 is slidably located within the body 1. A seal 6 is mounted on the innermost end 7 of the plunger to define at the closed end of the body a sealed chamber 8 within which the ingredients to be mixed may be mixed in a sealed, sterile environment. Conveniently, the mixing of the ingredients within a sealed chamber has the effect of ensuring that none of the ingredients are spilled irrespective of the force which is applied in agitating the ingredients within the chamber.

The body 1 comprises an elongate tubular casing 10 closed at one end 11 and may be constituted by the outer tube of a standard 20ml medical syringe including radially outward pressure flanges 12 at the open end thereof and a luer outlet nozzle 13 extending outwardly from the closed end 11. The outlet 13 has a central passageway therethrough which communicates with the interior chamber 8 of the tubular casing 10 and has an external shape enabling a luer slip closure cap 16 having a knurled head 17 (Figure 4) to be friction coupled thereto for closing off the outlet. The cap 16 can be removed and replaced by an elongate dispensing tube 18 (Figure 3) enabling the mixed product to be dispensed from within the casing 10 into a relatively inaccessible location. The cap 16 has an embedded pin 19 which projects therefrom as shown in Figure 4 and fits into the outlet nozzle 13 of the syringe when the cap 16 is fitted so as to avoid dead space within the outlet nozzle.

The plunger 5 is illustrated in more detail in Figure 7(a) and is substantially a modified form of the usual plunger used in a surgical syringe, the modification being the provision of an elongate central aperture 40 extending through the plunger along an elongate central axis 41 of the plunger for receiving the agitator paddle 2 therethrough. A seal 42, preferably a hollow rubber seal as shown in Figure 7(b), is mounted on the innermost end 43 of the plunger which is inserted in the tubular casing. The seal 42 has an annular inwardly extending flange 44 at a location within the hollow seal corresponding to a recessed groove 45 located in external surface 46 of the seal. A major open end face 47 of the seal, when mounted on the plunger, is

arranged to abut a surface 48 of plunger groove 49 remote from the outermost end of the plunger, with the inner flange 44 of the seal 42 located within the plunger groove to hold the seal on the end 43 of the plunger. A frustoconical surface portion 50 of the seal is located across the end of the seal and projects outwardly from the plunger in the longitudinal axial direction of the plunger.

Outermost transverse end surface 51 of the frustoconical surface comprises an opening 52 of a central aperture extending through the seal for receiving the agitator 2 therethrough and for sealing the agitator relative to the plunger. Outermost end 53 of the plunger is also provided with radially outwardly extending pressure flanges 54.

The central aperture 52 of the seal 43 comprises the transverse outer surface of the frustoconical surface 50 of the seal and in use receives the agitator 2 therethrough so that there is provided an effective seal between the agitator and the plunger to maintain a sterile environment within the mixing chamber when the plunger is located in the tubular casing 10.

The agitator paddle 2 is illustrated more particularly in Figure 5 and is sufficiently long to extend outwardly of the open end of the tubular casing 10 when the agitator head hereinafter described is deep within the casing 10. This enables it to be gripped by an operator's hand for agitating the ingredients to be mixed.

A flat 20 (Figure 5(a)) is located intermediate opposed ends 21, 22 of the agitator paddle 2 for allowing excess gases to escape during sliding of the dispensing plunger to its correct location within the tubular casing 10 to provide a suitably sized mixing chamber 8. The flat allows easy movement, without having to remove the end cap 16, until a prescribed distance where the flat ends.

A head 25 is provided at the innermost end of the agitator paddle 2, the head 25 comprising a circular base 26 extending transversely to the longitudinal axis of the agitator rod and a tapered conical surface 27 extending from the base 26 and terminating at point 28. The diameter of the circular

base of head 25 is substantially identical with the internal diameter of the tubular casing so as to provide a snug fit therein, but not a sealed fit. Four slots 29 are provided through the head, each being angularly displaced from the next by 90°. The slots 29 have the effect of allowing, in use, sufficient shear forces to be applied to the constituents being mixed so as to effect efficient mixing thereof within chamber 8.

A diametrically extending aperture 30 is located through the agitator rod, towards outermost end 22 of the paddle 2 for receiving bar 4 as seen in Figure 6, the bar 4 having a spherical head 31 from which extends an elongate rounded shaft with a small taper lead 32 at end 33 remote from the spherical head to enable ease of entry into the transverse aperture 30 in the agitator paddle 2. The presence of the bar 4 facilitates movement of the agitator paddle 2 in the longitudinal and/or rotational directions to mix the constituent materials placed into the tubular casing.

Figures 8 and 9 illustrate a syringe holder 60 comprising two opposed end members 61, 62 spaced apart by two elongate spacers 63. The elongate spacers 63 are each fixedly attached at their opposite ends to the end members 61, 62.

One end member 61, the right-hand end member in Figure 8, comprises an annular outer support portion 65 which has an inwardly projecting annular flange 66 extending outwardly of the holder in an axial direction thereof with a central aperture 67 therein. The opposite end support 62 comprises a circular plate having a centrally located internally screw-threaded aperture 68 therein with a relatively small radially extending slot 69 which extends into the central aperture of the end support from external circumferential surface 70. The width of the slot is sufficient to receive therethrough the agitator paddle 2.

A pressure screw 71 is shown in Figure 9 and has a screw threaded shank 72 which is adapted to be screw threadedly engaged with the internally threaded aperture 68 in end support 62 of the syringe holder 60. The shank 72

has a knurled cylindrical head 73 from which four pins 74 (Figures 2 and 3) extend radially outwardly at an angular spacing of 90° thereabout for turning the pressure screw. A bone 76 extends through the shank 72 for receiving the agitator paddle shaft 20.

When an operator wishes to use the mixing and delivery device which is described above, the operator takes the tubular casing 10 and mounts an end cap 16 on the outlet or luer nozzle 13 of the syringe to seal the outlet. The agitator paddle is then inserted into the tubular casing 10 and a conventional wide mouth funnel (not shown) is located over the shaft of the agitator paddle 2 and into the tubular casing. The contents of, for example, a 10 gram package of BoneSource powder is added to the tubular casing via the funnel and then a measured quantity of say 2.5 mls of liquid curing agent is also added to the tubular casing via the funnel. The funnel is then removed and the plunger 5 is inserted into the tubular casing having first ensured that the agitator paddle shaft is passed through the central aperture 52 of the seal 43 and through the elongate aperture 40 through the plunger to extend outwardly from the outermost end 53 of the plunger opposed to that end on which the seal is mounted. As the plunger 5 is moved inwardly of the tubular casing 10, pressure of air within the now closed tubular casing acts to increase resistance against inward movement of the plunger. However, before such movement is further prevented by the compressed air, the seal at the end of the plunger locates with the flat 20 on the agitator paddle 2 and gases are allowed to escape from the sealed chamber 8 within the tubular casing 10 whereupon the plunger 5 is movable further along the agitator paddle 2 into the tubular casing until the seal meets the normal circular cross-section of the agitator paddle and reseals the chamber 8. The plunger 5 is then moved forward until the pressure of air within the chamber prevents further inward movement of the plunger. At this point a defined sealed mixing chamber 8 is located within the tubular casing 10. The bar 4 shown in Figure 6 is then inserted and the agitator paddle 2 is then gripped in an operator's hand and rotated or briskly

moved in the longitudinal direction of the paddle to cause mixing of the powder/liquid constituents.

Dry unmixed powder will offer considerable resistance to the movement of the agitator rod. This will decrease as the mixture becomes more thoroughly mixed. Complete mixing is achieved when the agitator paddle can be moved through the BoneSource from one end to the other of the mixing chamber. The mixture at this point should have a consistency similar to that of toothpaste.

In the event that complete mixing is not achieved or that the consistency is more viscous than desired, up to 0.5 mls of liquid curing agent can be further added. This may be achieved by removing the end cap from the luer outlet nozzle and introducing the liquid curing agent by means of a conventional syringe with a needle. Before remixing the ingredients the end cap must be replaced. It is possible to add additional liquid curing agent dropwise until a desired consistency is obtained. However, it is essential to avoid adding too much fluid which may result in the mixed product being insufficiently viscous. The agitator paddle is then pulled sharply back onto the seal of the plunger to clear any excess mixture located between the agitator head and the seal and ensure that the agitator head 21 does not obstruct the nozzle outlet opening.

The end cap 16 may then be removed and the plunger depressed manually to extrude BoneSource from the luer output nozzle 13 directly to the site of application. If the application site has restricted access, a tube 18 of needle dimensions and having a female luer connector can be mounted upon the male luer output nozzle 13 to facilitate application of the BoneSource mixture.

If the female luer connector 18 is mounted on the tubular casing outlet nozzle 13, the narrow tubular nature of the connector may be such as to increase the back pressure within the tubular casing 10 to such an extent that it becomes difficult to extrude the mixed product. In this instance it is

recommended that the syringe be placed into the syringe holder of Figures 8 and 9 by placing the outlet end of the tubular casing to engage the inside of the right-hand end support of the holder shown in Figure 8 and arranging for the agitator paddle 2 to pass through the slot in the opposite holder end support 62 whereupon the pressure screw of Figure 9 may be placed over the agitator paddle and engaged with the internal screw thread of the end support 62. As the screw is rotated it moves through the end support 62 until free end 75 of the shank 72 engages the outermost end 53 of the plunger 5 and thereafter the plunger is moved inwardly of the tubular casing 10 with mechanical advantage which facilitates extrusion of the mixed product through the narrow tube of the elongate connector attached to the luer output nozzle 13.

The syringe holder 60 need not be provided with a slot 69 by which the agitator paddle 2 can be moved into the central screw threaded aperture 68 of the end support 62 to which the pressure screw 71 is mounted. The agitator paddle can alternatively be aligned with the aperture 68 at the end of the syringe holder and passed through the aperture and then the output end of the syringe can be placed in the other end of the holder. The pressure screw is then slid over the agitator paddle until it correctly mates with the thread of the syringe holder.

There has thus been described a device for mixing the constituents of BoneSource that can reliably produce a consistent and thoroughly mixed product. Advantageously, the possibility of accidental spillage during the mixing process is substantially eliminated and the delivery method is such as to enable BoneSource to be applied to voids in areas of restricted access. Moreover, the BoneSource is mixed and delivered using the same equipment so that there is no requirement for the transfer of BoneSource from the mixing vessel to a separate delivery system.

The apparatus disclosed herein is intended to be used in a sterile environment and therefore some parts are preferably made of metal whilst

other parts such as the syringe may be made of plastics or rubber material. In this respect, the metal parts, in particular the agitator paddle 2, bar 4, holder 60 and pressure screw 71 are preferably of highly polished stainless steel. The remaining parts are preferably of polypropylene or other materials commonly used for construction of medical devices, other than the seal 43 which is of a rubber material which may be a synthetic rubber or a natural rubber material.

Whilst the invention has been described in the foregoing by reference to a specific embodiment, it is to be appreciated that the described embodiment is exemplary and that modifications and variations thereto can readily be made without departure from the spirit and scope of the invention as set forth in the appended claims. For example, as shown in Figures 10 and 11 the end cap can advantageously be manufactured as a two piece assembly to facilitate cleaning and sterilization, the two pieces 100 and 101 being shown separately in Figure 10 and being shown in use in Figure 11 attached to the outlet nozzle 13 of the syringe body 10. Furthermore, the head of the agitator could be modified, for example as shown in Figures 12a and 12b where there are four additional shorter slots between the slots of the agitator head as shown in Figure 5b. Another possible modification would be to provide an additional spacer 63 in the syringe holder of Figure 8 or to form an equivalent spacer structure of sheet metal.

CLAIMS

1. An apparatus for mixing and delivery of constituent materials, said apparatus comprising first and second relatively moveable body portions (6,10) which together are capable of defining a mixing chamber (8) therebetween, and agitator means (2) locatable in the mixing chamber for mixing together ingredients introduced into said mixing chamber, characterised in that the agitator means includes a limited region (20) intermediate opposite ends thereof for allowing gas release from the mixed ingredients and being arranged to extend externally of the mixing chamber for enabling actuation of the agitator means and the body portions being movable relative to each other to reduce the volume of said mixing chamber for dispensing mixed ingredients therefrom.

2. An apparatus as claimed in claim 1, wherein said agitator means comprises an elongate shaft (2) arranged to extend in the longitudinal direction of the chamber.

3. An apparatus as claimed in claim 2, wherein the elongate shaft (2) has a head (25) mounted transverse to the direction in which the elongate shaft extends.

4. An apparatus as claimed in claim 3, wherein the head (25) of the agitator is conical with slots (29) for the passage therethrough of the constituents being mixed.

5. An apparatus as claimed in claim 3 or 4, wherein the head is circular with radially extending slots (29).

6. An apparatus as claimed in any of claims 2 to 5, wherein the limited region (20) is intermediate the opposite ends of the agitator shaft and includes reduced thickness portion having a flat surface to provide a gap between the agitator shaft and the second relatively movable portion to facilitate passage of gas from the mixing chamber.

7. An apparatus as claimed in any preceding claim, wherein the dispensing means comprises sealing means for sealing contact with the walls of the mixing chamber to seal the chamber.

8. An apparatus as claimed in any preceding claim, wherein the dispensing means comprises a plunger (5) and the agitator means (2) is arranged to pass sealingly through an aperture in the plunger.

9. An apparatus as claimed in any preceding claim, wherein the chamber (8) has an outlet through which mixture within the chamber can be dispensed.

10. An apparatus as claimed in claim 9, wherein the outlet is a luer outlet (13).

11. An apparatus as claimed in claim 9 or 10, wherein the chamber outlet (13) has an externally applied cap (16) for sealing the outlet when mixing the materials.

12. An apparatus as claimed in claim 9 or 10, wherein an elongate dispensing tube (18) is mounted to the outlet externally of the chamber to enable mixed materials to be dispensed into limited access locations through the tube to facilitate packing of a bone void into which the tube can be directed.

13. An apparatus as claimed in claim 12, wherein the elongate dispensing tube (18) is a needle.

14. An apparatus as claimed in any preceding claim, wherein the first and second body portions comprise a hollow syringe body (10) and a plunger (5) sealingly engageable within the body, the plunger having an elongate passage therethrough for the agitator means (2).

15. An apparatus as claimed in any preceding claim, further comprising a support (60) in which the apparatus is locatable and means (71) provided on or in the support for enabling mixed material to be dispensed with a mechanical advantage.

16. An apparatus as claimed in claim 15, wherein the support (60) includes an elongate screw-threaded member (72) which can be turned to effect relative movement of the two body portions of the apparatus.

17. An apparatus as claimed in claim 16, wherein the screw-threaded member (72) is threadedly engaged with an aperture (69) in an end portion of the support, and an open slot is provided in said end portion communicating with said aperture, said slot being dimensioned to allow passage of the externally extending part of the actuator therethrough.

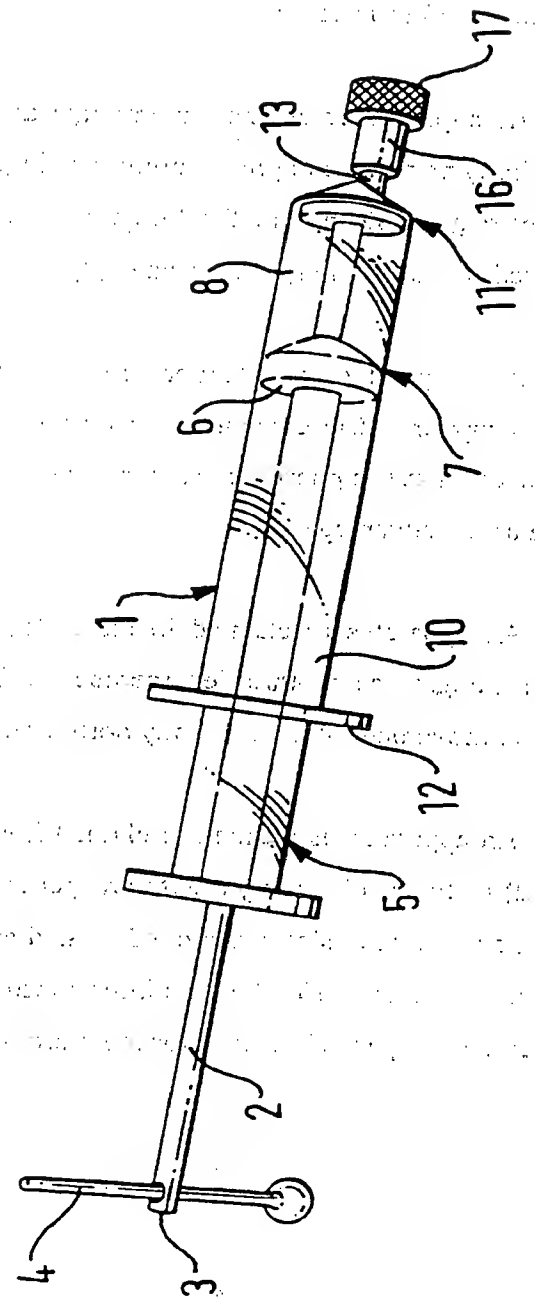


FIG. 1

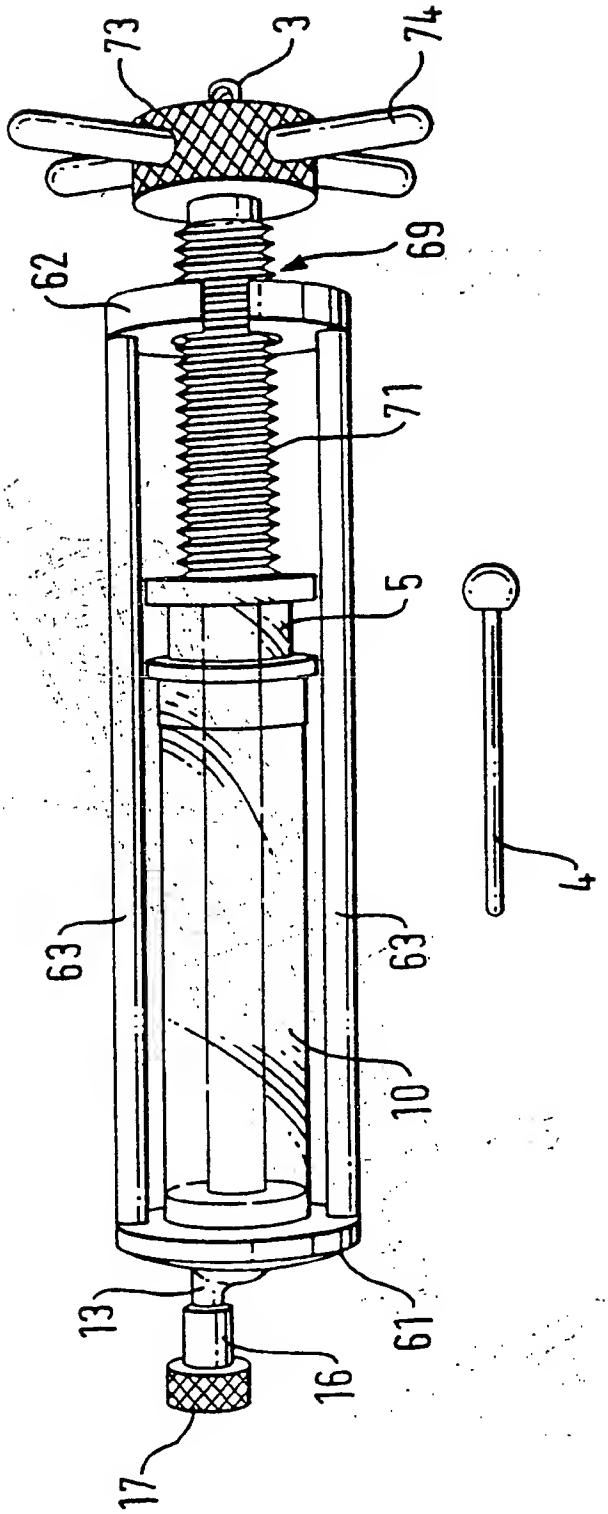
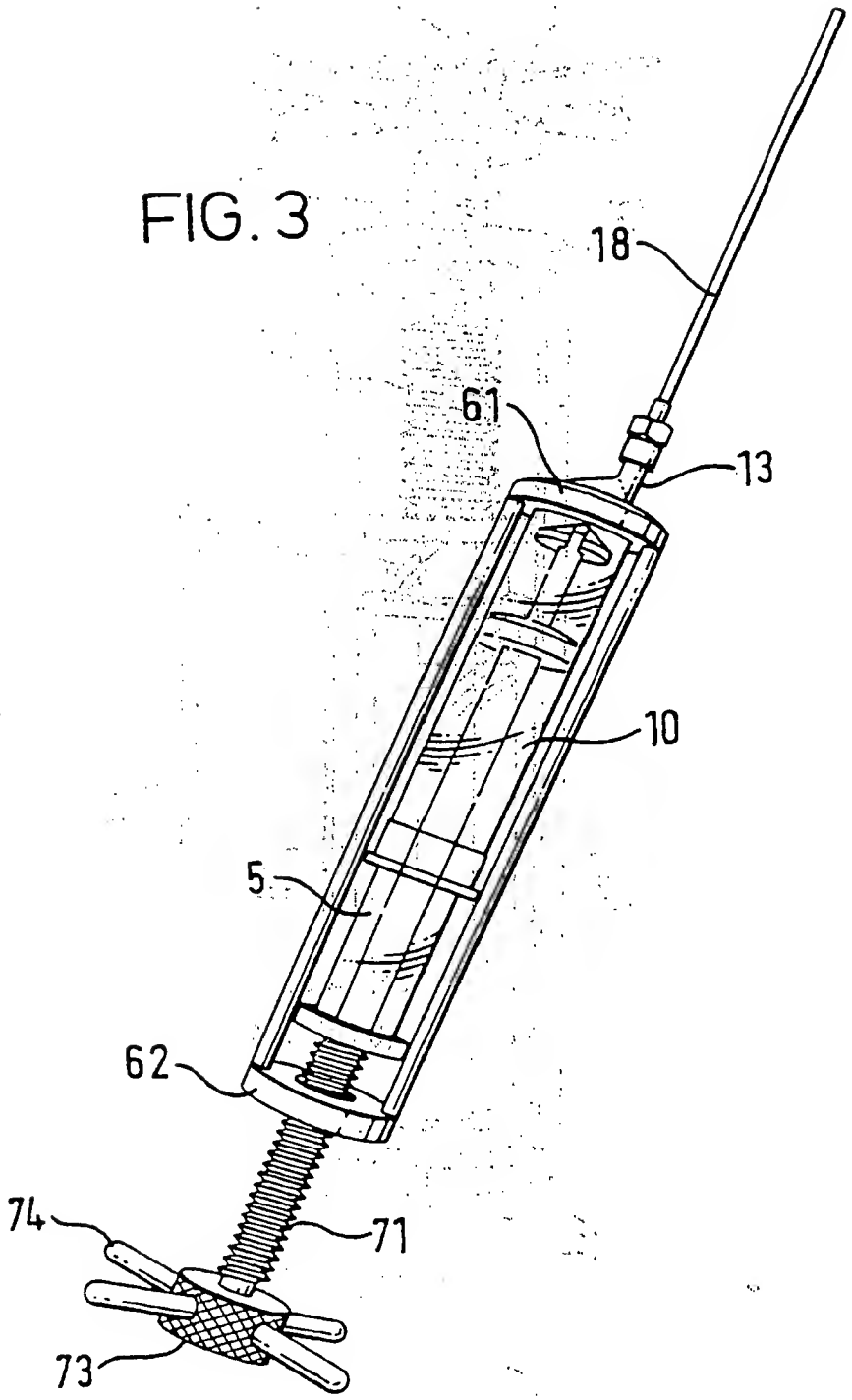


FIG. 2

FIG. 3



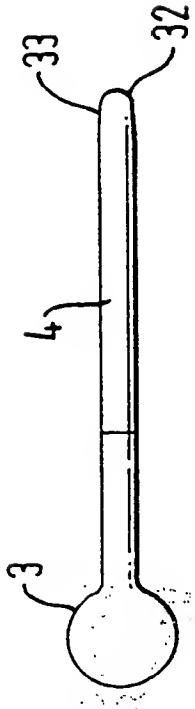


FIG. 6

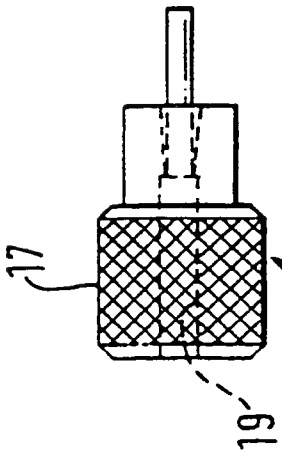


FIG. 4

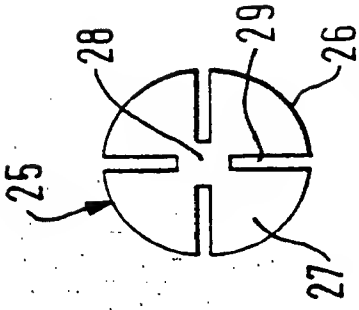


FIG. 5(b)

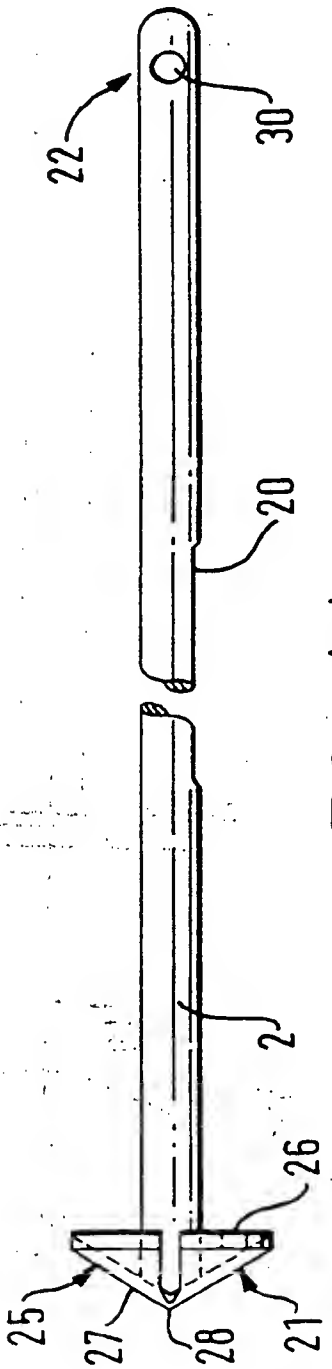


FIG. 5(a)

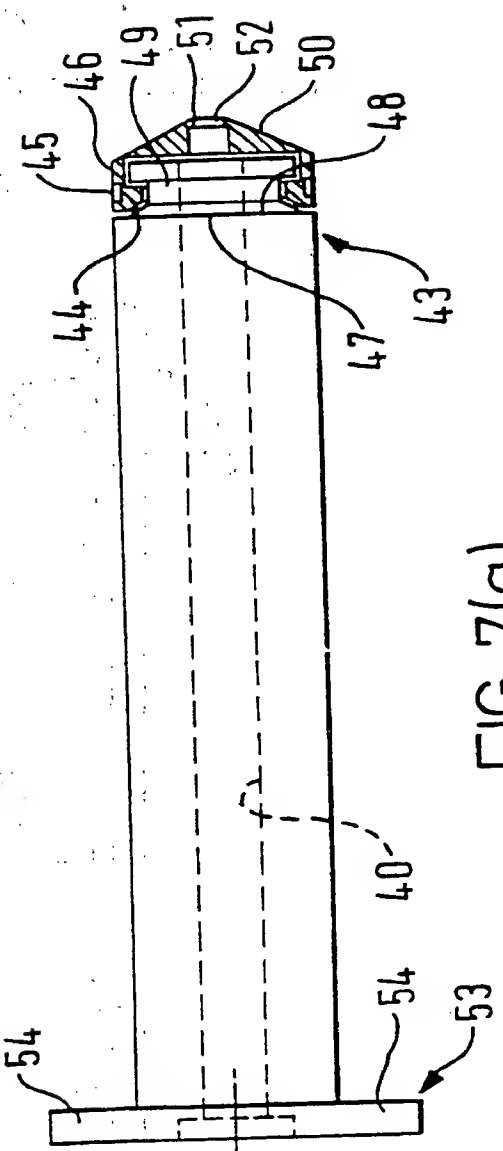


FIG. 7(a)

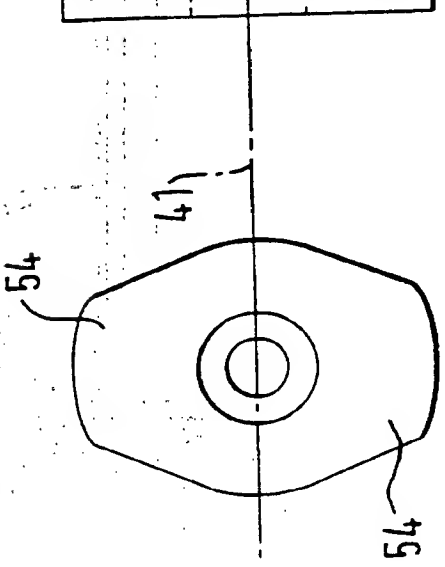


FIG. 7(b)

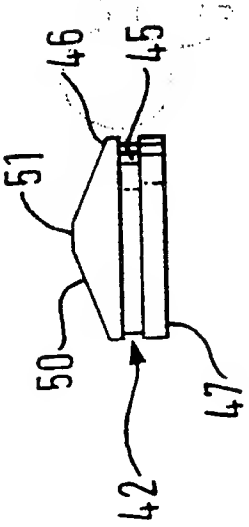


FIG. 7(c)

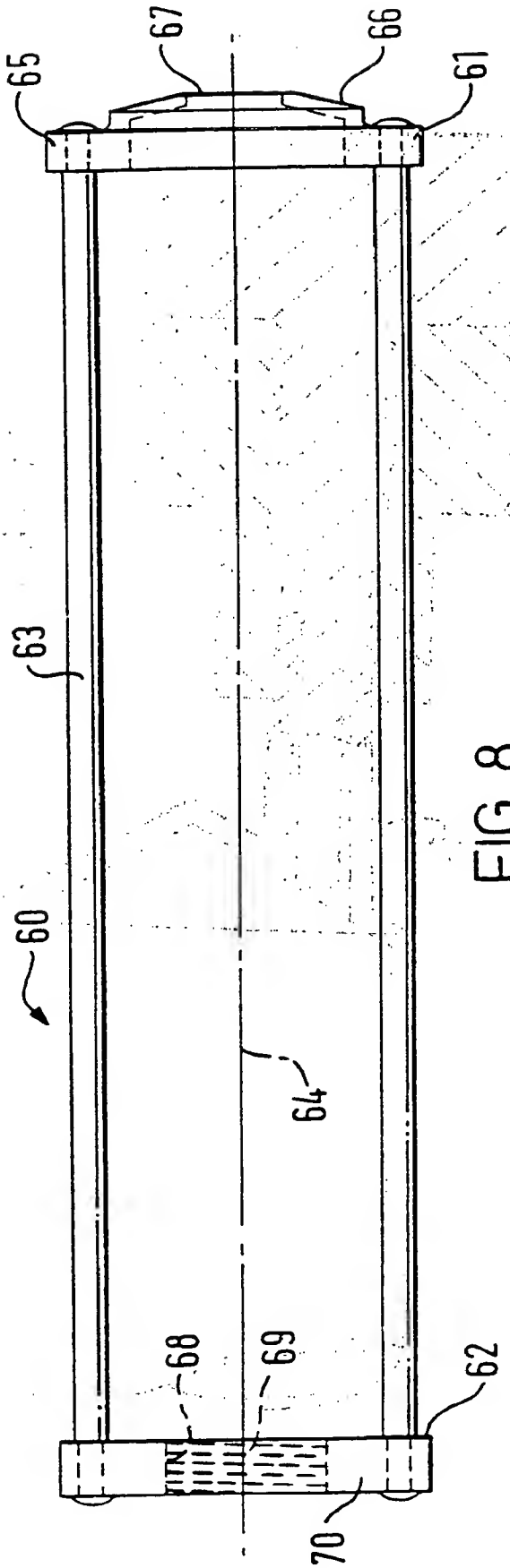


FIG. 8

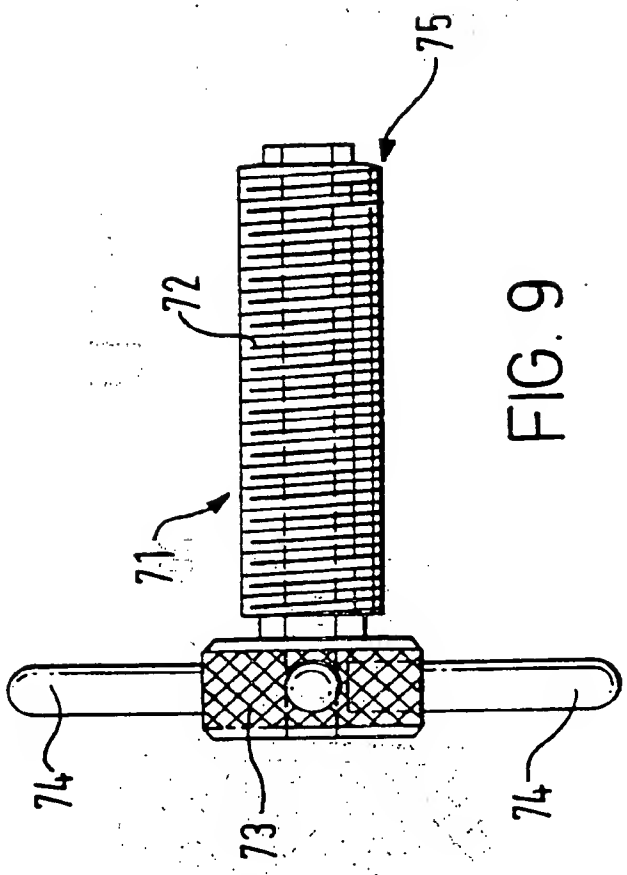


FIG. 9

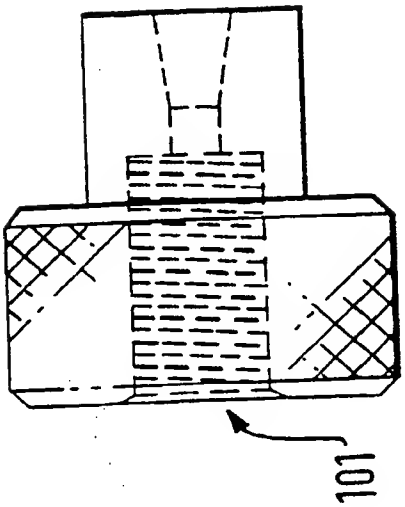
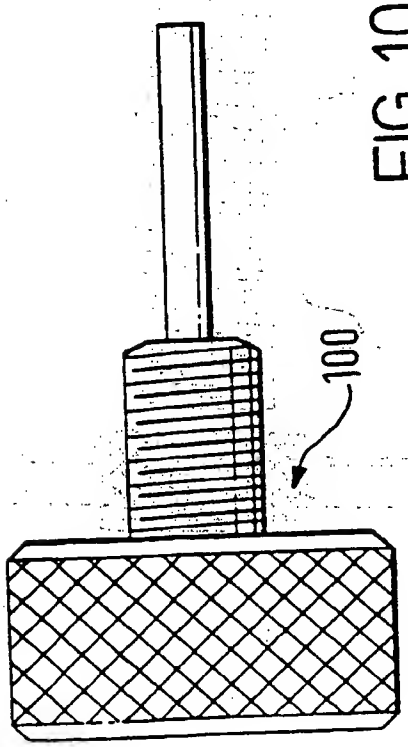


FIG. 10



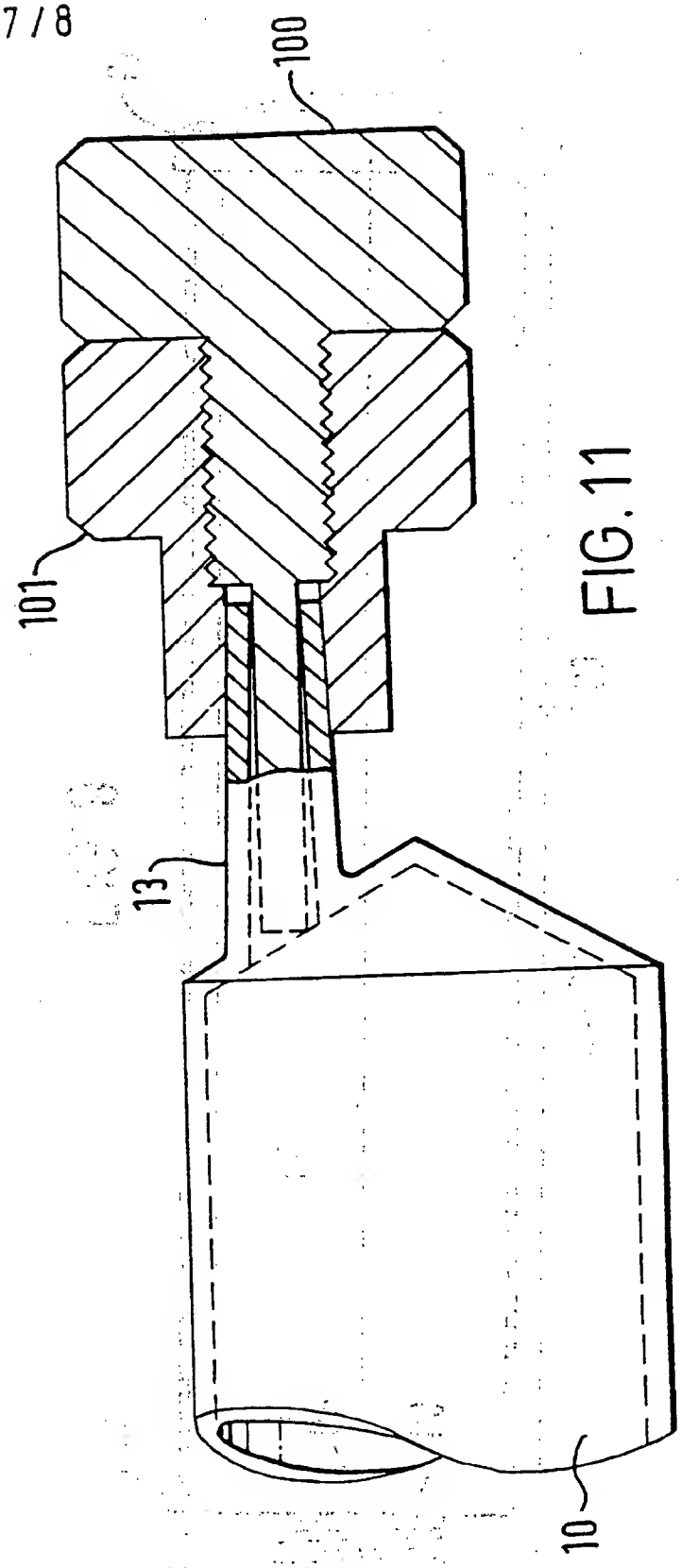


FIG. 11

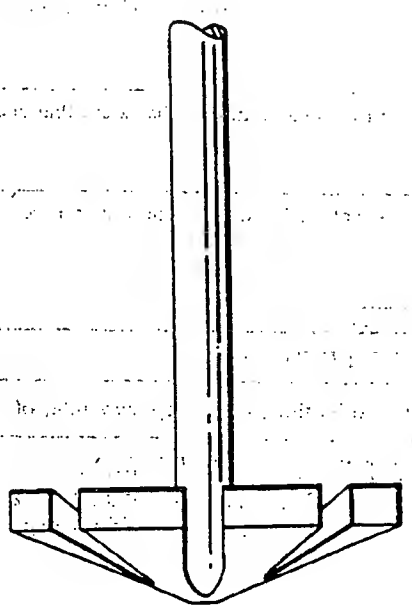


FIG.12(a)

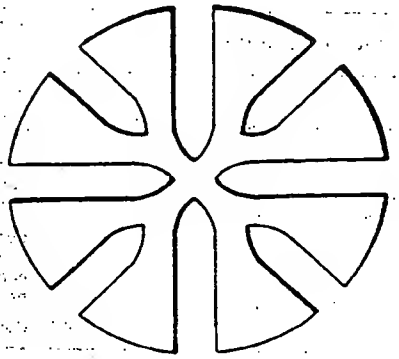


FIG.12(b)

INTERNATIONAL SEARCH REPORT

tional application No.
PCT/GB 99/01922

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: B01F 3/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: B01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC, PAJ, US FULLTEXT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3546129 A (ROBERT H. BERG ET AL), 8 December 1970 (08.12.70), column 2, line 57 - column 3, line 6; figures 1,3 --	1-3,9-11,14
X	GB 1340483 A (THE BRITISH UNITED SHOE MACHINERY COMPANY LIMITED), 12 December 1973 (12.12.73), page 2, line 70 - page 3, line 43, the figure --	1,2,9-11,14
A	US 5252301 A (THOMAS NILSON ET AL), 12 October 1993 (12.10.93), column 1, line 5 - line 15; column 2, line 45 - line 68, figures 2-4 --	1-17

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 October 1999	03. 11. 1999
Name and mailing address of the International Searching Authority European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel(+31-70)340-2040, Tx 31 651 epo nl, Fax(+31-70)340-3016	Authorized officer WIVA ASPLUND/ELY

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/GB 99/01922

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 9013264 A	15/11/90